

Message Text

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PAGE 01 STATE 137415
ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 EA-12 NEA-11 ISO-00 OES-07
SIG-03 /066 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO

APPROVED BY OES/ENP/EN: WJWALSH, III

DHEW/PHS/OASH/OIH: MKEFAUVER

ARA/CEN:LPFEIFLE(INFO)

EA/J:EFEATHERSTONE(INFO)

NEA/IAI:MANDERSON(INFO)

ARA/AND/C:DCOX(INFO)

EUR/NE:WNEWLIN(INFO)

EUR/NE:RWOODS(INFO)

EUR/WE:AHUGHES(INFO)

EA/ANP:TWAJDA

EUR/NEA:SWORREL

-----025496 311844Z /72

P 311829Z MAY 78

FM SECSTATE WASHDC

TO AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY TOKYO PRIORITY

AMEMBASSY TEL AVIV PRIORITY

AMEMBASSY BOGOTA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY CANBERRA PRIORITY

AMEMBASSY LONDON PRIORITY

UNCLAS STATE 137415

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, GT, JA, IS, CO, BE, SW, SP,

SUBJECT: FDA ADVISORY - CATHETER TRAYS CONTAINING DEFECT-

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IVE STERILE GLOVES (RECALL T-097-8)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED - CENTRASIL SILICONE ELASTOMER CENTRAL
VENOUS CATHETER WITH ACCESSORIES TRAYS - PRODUCT NO. 2N1500

CENTRASIL SILICONE ELASTOMER CENTRAL VENOUS CATHETER WITH

GLOVES - PRODUCT NO. 2N1510

INTRASIL SILICONE ELASTOMER CATHETER PLACEMENT UNIT WITH
ACCESSORIES - PRODUCT NOS. 2N1619 AND 2N1620

CATHETER TRAYS ARE USED FOR LONG-TIME INFUSION OF TOTAL
DIET INTO VENOUS SYSTEM ON PATIENTS WHO CANNOT RECEIVE
ORAL NOURISHMENT AND ARE RESTRICTED TO SALE BY OR ON
ORDER OF A PHYSICIAN. EACH CASE CONTAINS 10 TRAYS.

2. PRODUCT IDENTIFICATION - BRAND NAMES: CENTRASIL AND
INTRASIL

NAME OF FIRM ON LABEL: MANUFACTURED BY VICRA DIVISION
OF TRAVENOL LABORATORIES, INC., DALLAS, TEXAS. MARKETED
BY TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS.

LOT NUMBERS: (A) PRODUCT CODE 2N1500 - LOTS 757, 764,
770, 784, 788, 798, 805, 815, 827, 833, 854, 922, 947,
955, 966, 983, 990, 1010, 1014, 1032, 1039, 1055, 1062

(B) PRODUCT CODE 2N1510 - LOTS 818, 843, 868, 991, 1003,
1049, 1068, 1087, 1103

(C) PRODUCT CODE 2N1619 - LOT 961; PRODUCT CODE 2N1620 -
LOTS 791, 794, 822, 835, 858, 877
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3. MANUFACTURER/RECALLING FIRM - VICRA DIVISION OF
TRAVENOL LABORATORIES, INC., 2919 BLYSTONE, DALLAS,
TEXAS 75220. (NOTE: GLOVES CONTAINED IN KITS WERE
MANUFACTURED BY DAYTON FLEXIBLE PRODUCT, DIVISION OF
TRAVENOL LABS., INC., DAYTON, OHIO AND SUPPLIED TO
VICRA BY TRAVENOL LABS, KINGS TREE, SOUTH CAROLINE -
REFER TO RECALL T-076-8).

4. REASON FOR RECALL - CATHETER TRAYS CONTAIN ADULTER-
ATED STERILE LATEX GLOVES--DEFECTIVE QUALITY OF LATEX
FORMULATION IN THE GLOVES HAS RESULTED IN DETERIORATION
OF THE GLOVES' TENSILE STRENGTH AND DEVELOPMENT OF
PINHOLES, LARGE HOLES AND TEARS IN THE GLOVES. A REP-
RESENTATIVE OF VICRA NOTIFIED FDA OF THE RECALL BY
TELEPHONE. FOLLOW-UP VISIT TO THE FIRM ON APRIL 11
DISCLOSED THE FIRM HAD BEEN NOTIFIED OF THE DETERIORATION
PROBLEM BY TRAVENOL LABS., DEERFIELD, ILLINOIS, AND WAS
INSTRUCTED BY TRAVENOL ON MARCH 16 TO INITIATE A RECALL
OF ALL LOTS CONTAINING THE DEFECTIVE GLOVES. ALTHOUGH
FIRM PROVIDED THE LOT NUMBERS INVOLVED IN THIS RECALL,
THE RECALL LETTERS DO NOT SPECIFY LOT NUMBERS BUT STATE

THE ACCOUNTS ARE TO DESTROY GLOVES IN ALL TRAYS OF THE FOUR PRODUCT CODES.

5. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED INSTRUCTIONS FROM FIRM REGARDING DISPOSITION OF TRAYS INVOLVED IN RECALL. ANY QUESTION REGARDING RECALL SHOULD BE REFERRED TO FIRM DIRECTLY.

6. FOREIGN CONSIGNEES AS FOLLOWS:

FARMACEUTICA AMICELLO PRODUCT CODE: 2N1500
APARTADO 515
GUATEMALA CITY, GUATEMALA

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CONSIGNEE: PRODUCT CODE:

TRAVENOL PACIFIC LTD. 2N1500
TBR BLDG. ROOM 1119
5-7 KOJIMACHI, CHIYODA-KU
TOKYO 102 JAPAN

SUMITOMO CHEMICAL CO. 2N1619
40 2-CHOME DOSHOMACHI
HIGASH-KU, OSAKA, JAPAN

TRAV TRADING CO. LTD. 2N1500
ASHDOD, ISRAEL 2N1510

LABORATORIOS TRAV S.A. 2N1500
APARTADO AEREO 2446
CALI COLOMBIA

S.A. TRAVENOL LABORATORIES N.V. 2N1500
BOULEVARD D. HOURAING 2N1510
7860 LESSINES, BELGIUM 2N1619

TRAVENOL LABORATORIER A B 2N1510
BOX 20115 S161-20
BROMMA SWEDEN

LABORATORIOS HERPERIA 2N1510
APARTADO DE CORREOS 765
VALENCIA 14 SPAIN

TRAVENOL LABORATORIES PTY LTD. 2N1500
P.O. BOX 88 2N1510
TOONGABBIE N S W 2146 AUS. 2N1620
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TRAVENOL LABORATORIES LTD. 2N1510

CAXTON WAY THETFORD 2N1620

NORFOLK ENGLAND CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptoning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 31 may 1978
Decapton Date: 01 jan 1960
Decapton Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE137415
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780227-1050
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t1978052/aaaaabiu.tel
Line Count: 179
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: e6bfba96-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2571669
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - CATHETER TRAYS CONTAINING DEFECT- UNCLASSIFIED UNCLASSIFIED
TAGS: OGEN, ETRD, EIND, TBIO, GT, JA, IS, CO, BE, SW, SP
To: GUATEMALA TOKYO MULTIPLE
Type: TE
vdkgvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/e6bfba96-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014